

REMARKS

Status Summary

Currently, claims 1-36 are pending. Claims 27-36 are presently withdrawn by the present Official Action. Claims 1-26 presently stand rejected. Upon entry of this amendment, claims 1, 5, 6, 21, and 23 will be amended. Claims 27-36 are canceled without prejudice in response to a Restriction Requirement. New claims 37-40 have been added. Thus, upon entry of this amendment, claims 1-6, 21-26, and 37-40 will be pending. Reconsideration of the application and entry of the amendment is respectfully requested.

Claim Rejection - 35 U.S.C. § 112

Claims 1-6 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time of the application was filed had possession of claimed invention. In particular, the Examiner asserts that independent claims 1, 5, and 6 contain new subject matter that the intrafocal plate "consists" of the recited features, while the specification recites that the intrafocal plate "comprises" such features. It is respectfully submitted that, with the amendments above, the Examiner's concerns regarding claims 1-6 have been addressed. Applicant, however, also submits that the specification specifically recites the features as previously claimed in the claims 1-6 in combination with one another.

Therefore, even if the specification does recite "comprising" in conjunction with the features, it must therefore also teach that it consists of those features as well, thereby justifying the claim language of "consisting of." Therefore, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-6 under 35 U.S.C. §112, first paragraph.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,467,793 to Ender (hereinafter, "Ender"). Applicant notes that claim 3 has previously been canceled. This rejection is respectfully traversed.

Recitation of the Independent Claims Rejected under 35 U.S.C. § 102(b)

Independent claim 1 recites a longitudinally extending intrafocal plate for securing bone fractures. The intrafocal plate comprises a flat, elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, a leading end, and a trailing end and sized to overlay a fracture site. The elongated intrafocal plate has a longitudinally extending intrafocal resilient body element secured with the intrafocal plate element adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is secured to the surface of the plate element. Also, the resilient body element is secured with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is secured to the surface

of the plate element and the trailing end of that surface. The overhanging heel extends downwardly below the location at which the resilient body element is secured to the surface of the plate element. The heel serves to help stabilize the fracture site. The resilient body element is formed to extend generally in a lengthwise direction of the surface in a sinuous shape depending downwardly and outwardly from the bottom of the surface and wherein the other end of the resilient body element defines a pin element.

Claim 5 recites an intrafocal plate for securing bone fractures. The intrafocal plate comprises a flat, elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. The intrafocal plate has a longitudinally extending intrafocal resilient body element integral to the surface adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is integral to the surface of the plate element. Also, the resilient body element is integral with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is integral to the surface of the plate element and the trailing end of the surface. The overhanging heel extends downwardly below the location at which the resilient body element is integral to the surface of the plate element. The heel serves to help stabilize the fracture site. The other end of the body element defines a pin with the intrafocal plate including one or more screws for insertion through one or more apertures defined in surface of the plate element. The resilient body element defines a substantially sinuous shape according to a side elevation view of the resilient body element and a

substantially straight shape according to a top elevation view of the resilient body element.

Independent claim 6 recites a longitudinally extending intrafocal plate for securing metaphyseal bone fractures. The intrafocal plate comprises a flat, elongated intrafocal plate element having a surface at one end thereof with one or more apertures therein in defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. At least two screws extend through the flat, elongated intrafocal plate. The intrafocal plate has a longitudinally extending intrafocal resilient body element affixed to and depending from the trailing end of the surface so that the body element forms an acute angle with the surface and extends generally in a lengthwise direction of the surface. The body element is adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is affixed to the surface of the plate element. Also, the resilient body element is affixed with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is affixed to the surface and the trailing end of the surface. The overhanging heel extends downwardly below the location at which the resilient body element is affixed to the surface of the plate element. The heel serves to help stabilize the fracture site. The body element defines a shoulder at one end at the juncture of the body element and the surface with a pin at the other end of the body element. The resilient body element has a sinuous shape orthogonal to the surface of the plate element. This body element has a first portion, a second portion and a third portion. The first portion of the body element

curves away from the plate element. The second portion of the body element curves toward the plate element. The third portion of the body element curves away from the plate element.

Support for the amendments to the claims 1, 5, and 6 can be found throughout the application as filed. For example, support for the amendments to these claims is found at Figures 9A and 9B (showing top elevation and side elevation views readily understood by those of skill in the art to be orthogonal planes). As recited in the specification of the originally filed patent application, "Figures 9A and 9B depict yet another type of the invention generally designated **50** and comprising plate element **50A** having body element **50B** extending outwardly and downwardly therefrom in a sinuous pathway so as to contact the front portion of the bone in order to secure plate element **50A** against the fracture site of the bone." (See page 17, lines 5-9 of the originally filed patent application.)

Applicant's Arguments Against the Rejections under 35 U.S.C. § 102(b)

Applicant respectfully submits that Ender does not anticipate independent claims 1, 5, and 6 or the claims that depend therefrom. In particular, Ender does not disclose all the features of claims 1, 5, and 6.

Ender discloses a device for reducing or repositioning and fixing of pertrochanterous and subtrochanterous fractures. The device has at least one bone nail of resilient material. The one or more bone nails are bent at their proximal end portions and are insertable into the medullary canal of a bone through an impact hole formed in the bone. The one or more bone nails are intended to contact, under tension,

the apex of the bent portion the wall of the medullary canal, opposing the impact hole. The distal end of the one or more bone nails are provided with a coupling member allowing a positive connection for rotation with an impact tool. An insert member is placed in the impact hole and includes a tubular guide channel through which the bone nails pass and a means to prevent shifting of the insert member in the impact hole.

In particular, Ender discloses a device that includes resilient bone nails **4** and an insert member **5** that is a separate modular component from the resilient bone nails **4**. The bone nails **4** are provided at their respective distal ends with a coupling member (not shown). The insert member **5** has a guide channel **6** and a flange contacting the outer surface of the bone **1**. (See Ender, col. 4, line 41- col. 5, line 9.) In particular, Ender discloses that "the insert member **5** has a guide channel **6** (see Figures 2 to 7) which is arranged such that the nails, when forcibly introduced, run into the medullary canal **3** in the desired manner. The guiding channel **6** is formed of a tubular piece **8** connected with the flange **7**. In use, the flange **7** contacts the outer surface of the bone and prevents the insert member **5** from entering the medullary canal for "too great a distance." (See Ender, col. 4, line 65- col. 5, line 4.) The insert member **5** is inserted into the impact hole whereupon the bone nails **4** are forcibly introduced and rotated for reducing or repositioning the fractured area. (See Ender, col. 4, lines 56-59.)

Ender does not disclose, teach, or suggest an intrafocal plate including a flat, elongated intrafocal plate element having a surface defining a top and a bottom, as well as a resilient body element formed so as to extend generally in a lengthwise direction of the surface in a sinuous shape depending downwardly and outwardly from the bottom of the surface as recited in claim 1. Ender also does not disclose, teach, or suggest an

intrafocal plate including a flat, elongated intrafocal plate element having a surface defining a top and a bottom, as well as a resilient body element that defines a substantially sinuous shape according to a side elevation view of the resilient body element and a substantially straight shape according to a top elevation view of the resilient body element as recited in claim 5. Further, Ender also does not disclose, teach, or suggest an intrafocal plate that includes a flat, elongated intrafocal plate element having a surface defining a top and a bottom, as well as a resilient body element that has a sinuous shape orthogonal to the surface of the plate element with the body element having a first portion, a second portion and a third portion as recited in claim 6. With regards to claim 6, Ender additionally does not disclose, teach, or suggest that the first portion of the body element curves away from the plate element, the second portion curves toward the plate element, and the third portion of the body element curves away from the plate element as recited in claim 6.

For at least the reasons set forth above, Ender does not anticipate claims 1, 5, and 6. Since claims 2 and 4 depend from claim 1, these claims are also not anticipated by Ender. Applicant, therefore, respectfully requests that the rejections of claims 1, 2, and 4-6 under 35 U.S.C. § 102(b) be withdrawn and the claims allowed at this time.

Claim Rejections – 35 U.S.C. § 103

Claims 21-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ender in view of U.S. Patent No. 4,135,507 to Harris (hereinafter, "Harris"). This rejection is respectfully traversed.

Recitation of the Independent Claim Rejected under 35 U.S.C. § 103(a)

Independent claim 21 recites an intrafocal plate for stabilizing a fracture site. The intrafocal plate includes a plate element having a first end and a second end. The intrafocal plate also includes a body element extending downwardly and outwardly from the plate element in a first plane. The body element has a sinuous shape in the first plane and is connected between the first end and the second end of the plate element. The body element has a first portion, a second portion and a third portion, wherein the first portion curves away from the plate element, the second portion curves toward the plate element and the third portion curves away from the plate element. The second end of the plate element stabilizes the fracture site.

As above, support for the amendments to the claim 21 is found throughout the application as filed. Support for the amendments to the claim is found, for example, at Figures 9A and 9B (showing top elevation and side elevation views readily understood by those of skill in the art to be orthogonal planes). Additionally, as recited in the specification of the originally filed patent application, "Figures 9A and 9B depict yet another type of the invention generally designated **50** and comprising plate element **50A** having body element **50B** extending outwardly and downwardly therefrom in a sinuous pathway so as to contact the front portion of the bone in order to secure plate element **50A** against the fracture site of the bone." (See page 17, lines 5-9 of the originally filed patent application.)

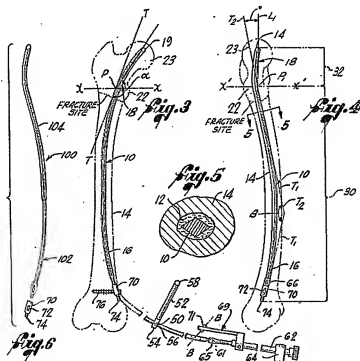
Arguments Against the Rejections under 35 U.S.C. § 103

As discussed above, Ender does not disclose, teach or suggest an intrafocal plate that includes a body element extending downwardly and outwardly from the plate element in a first plane with the body element having a sinuous shape in the first plane and connected between the first end and the second end of the plate element and the body element having a first portion, a second portion and a third portion as recited in claim 21. Ender additionally does not disclose, teach, or suggest that the first portion of the body element curves away from the plate element, the second portion curves toward the plate element, and the third portion of the body element curves away from the plate element as recited in claim 21. Harris does not overcome the shortcomings of Ender.

Harris discloses a condylocephalic nail is designed to attain an optimal nail position in the head-neck fragment of the femur. To this end, the nail is provided with a curve as viewed in the frontal or anterior-posterior (AP) plane, which places the upper portion of the nail adjacent to the medial cortex at the level of the lesser trochanter and also places it approximately parallel with the primary trabeculae of the head, i.e., at an included angle of about 160° with respect to the shaft of the femur. The relatively high angle of the upper end of the nail was chosen in order to place it closely parallel to the stress lines encountered by the head and neck of the femur during ambulation. In order to achieve accurate rotatory alignment and to obviate external rotatory malalignment of the femur, the nail is provided, as viewed from the medial side, with a gentle S-shaped curve, in which the upper end or head of the S is formed with an anteversion curve of

between about 5°-15° and the remainder, or body portion, of the S-shaped curve is formed with an included anterior-posterior angle of between about 155°-175°. The optimum angle for the S-shaped curve is about 8° for the anteversion portion and about 170° for the included anterior-posterior angle.

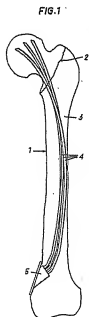
According to Harris, the S-shape shown in Figures 4 and 6 (reproduced below) is provided for a specific purpose.



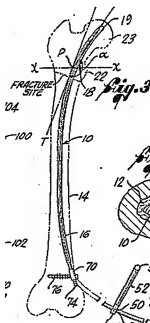
With respect to the medial-lateral plane, Harris teaches the use of the elongated S-shaped curve, in the medial-lateral view. For example, the incorporation of an anteversion angle γ in the proximal portion 18 of the nail, together with the use of anterior-posterior angle γ in the major distal portion of the curve 30, accommodates the normal curvature of the femur and that of the intermedullary canal in the femur to a

much greater extent than can planar nail(s). Harris states that the inclusion of such an anteversion angle γ in the proximal portion 18 of the nail and an anterior-posterior angle γ in the major distal portion of the curve 30 has been effective in achieving and maintaining rotatory alignment. (See Harris, col. 4, lines 35-43.)

In the other direction, which is the frontal or anterior-posterior (AP) direction discussed above, Harris provides a curve similar to the curve shown in Ender, which is also included for a particular purpose.



Ender, Fig. 1



Harris, Fig. 3

With respect to the anterior-posterior plane, Harris teaches that the nail provides a curve as viewed in the frontal or anterior-posterior (AP) plane, which places the upper portion of the nail adjacent to the medial cortex at the level of the lesser trochanter and

also places it approximately parallel with the primary trabeculae of the head, i.e., at an included angle of about 160° with respect to the shaft of the femur to attain an optimal nail position in the head-neck fragment of the femur. The relatively high angle of the upper end of the nail is chosen in order to place it closely parallel to the stress lines encountered by the head and neck of the femur during ambulation.

Therefore, Harris and Ender, alone or in combination, do not disclose, teach, or suggest an intrafocal plate including a body element extending downwardly and outwardly from the plate element in a first plane with the body element having a sinuous shape in the first plane and connected between the first end and the second end of the plate element and the body element having a curved first portion, a curved second portion and a curved third portion as recited in claim 21.

Moreover, there would be no reason to modify Ender and Harris to provide such features. For example, Harris teaches a shape similar to the shape that Ender uses in the direction the nails 4 extend from the insert member 5 – the anterior-posterior plane direction. In other words, both Harris and Ender utilize similar, arcuate shapes in the anterior-posterior plane direction. Indeed, Harris specifically indicates that one of ordinary skill in the art should use that shape in the anterior-posterior direction because it "places the upper portion of the nail adjacent to the medial cortex at the level of the lesser trochanter and also places it approximately parallel with the primary trabeculae of the head."

The S-shape that Harris utilizes is lateralized to accommodate the S-curvature of the femur shown in FIG. 4 of Harris. Thus, though the propriety of such combination is not acceded, if the configuration of Harris were applied to Ender, the combination would not result in the nails 4 of Ender extending in generally a lengthwise direction of the insert member 5 in a sinuous shape depending downwardly and outwardly from the insert member 5. In particular, Harris utilizes much the same approach as Ender in the anterior-posterior plane direction, and there is no reasonable guidance for deviating from such an approach in either reference. In fact, when read as a whole, the two references fail to address, and more likely teach away from, the sinuous features according to independent claim 21 as well as independent claims 1, 5, and 6 as amended. As set forth in MPEP § 2141.02, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. (See W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).) In considering Harris and Ender as a whole, it is clear that these references do not render obvious independent claim 21 or the claims that depend therefrom, or independent claims 1, 5, and 6 or the claims that depend therefrom.

For the reasons set forth above, claim 21 is not rendered obvious by Harris and Ender. Since claims 22-26 depend from claim 21, these claims are also not rendered obvious by the cited references. Accordingly, applicant respectfully submits that the rejections of claims 21-26 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

New Claims

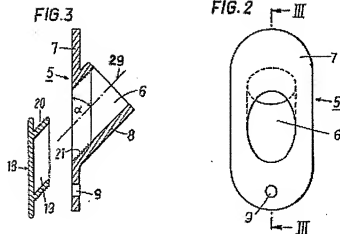
New claims 37-40 have been added by this amendment as indicated above. Claim 37 depends from claim 21. Claim 38 is an independent claim and recites an intrafocal plate for securing bone fractures. The intrafocal plate includes a resilient body element formed as an integral, single piece with an elongate plate element and extending downwardly from the bottom surface of the elongate plate element and in a lengthwise direction relative to the elongate plate element beyond the terminal end of the resilient plate element. The resilient body extends from the intermediate location of the elongate plate element such that the overhanging heel of the elongate plate element is located between the resilient body element and the trailing end of the elongate plate element.

As above, support for the claims 38-40 is found throughout the application as filed. For example, support for these claim is found at Figures 9A and 9B (showing top elevation and side elevation views readily understood by those of skill in the art to be orthogonal planes). Additionally, as recited in the specification of the originally filed patent application, "Figures 9A and 9B depict yet another type of the invention generally designated **50** and comprising plate element **50A** having body element **50B** extending outwardly and downwardly therefrom in a sinuous pathway so as to contact the front portion of the bone in order to secure plate element **50A** against the fracture site of the bone." (Page 17, lines 5-9 of originally filed patent application.)

Although not presently rejected, several reasons for allowing new claims 38-40 over the cited references are presented in order to expedite prosecution. For example,

new claim 38 relates, in part, to an intrafocal plate for securing bone fractures, the intrafocal plate including an elongate plate element defining an overhanging heel toward a trailing end configured to prevent over reduction of a fracture and to stabilize the intrafocal plate when inserted into a fracture site of a bone and a bottom surface that is configured to engage an outer surface of a bone. The intrafocal plate also includes a resilient body element formed as an integral, single piece with the elongate plate element that extends downwardly from the bottom surface of the elongate plate element and in a lengthwise direction relative to the elongate plate element beyond the terminal end of the resilient plate element. The resilient body extends from an intermediate location of the elongate plate element such that the overhanging heel of the elongate plate element is located between the resilient body element and the trailing end of the elongate plate element. For at least the following reasons, the cited references do not reasonably address such features.

For example, Ender is concerned with forming the nails **4** and the insert member **5** as separate pieces so that the nails **4** are able to be introduced through insert member **5**. For example, the insert member **5** is to serve as an abutment and prevent, when contacting the outer surface of the bone, the nails **4** from becoming shifted in direction to the medullary canal. The relatively short, tubular piece **8**, otherwise cited in the Office Action as being part of an integral "longitudinally extending intrafocal resilient body element" according to the claims, does not extend in a lengthwise direction beyond the flange **7** of Ender, nor is there any apparent reason for modifying the tubular piece **8** accordingly.



Applicant respectfully submits that to change Ender in the manner suggested would change the principle of operation of the device in Ender. MPEP § 2143.01 states that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. (See *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) and MPEP § 2143.01.) To modify Ender, or any reasonable combination of Ender and Harris, to form the nails 4 and the insert member 5 as integral pieces would change the principle of operations of the device in Ender. The methodology disclosed by Ender applies specifically to utilizing the insert member 5 as a guide for the nails 4 as they are introduced through the insert member 5. To change the device in Ender so that the insert member 5 was integral with the nails 4 would change how the insert member 5 and the device operate.

Additionally, such a modification would also not render the device in Ender unsatisfactory for its intended purpose. As set forth in MPEP § 2143.01, if proposed

modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (See In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).)

For at least such reasons, new claim 38 and the claims depending therefrom are allowable. Further, since claim 37 depends from claim 21 and claim 21 is allowable over the cited references for the reasons stated above, claim 37 is also allowable. Thus, it is respectfully submitted that new claims 37-40 are in condition for allowance. No new matter has been added.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the claims of the present application are now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

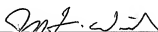
If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,
JENKINS, WILSON, TAYLOR, & HUNT, P.A.

Date: October 22, 2010

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JLW/DMS/gwc

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